MAC MURRAY & SHUSTER

VIA ELECTRONIC FILING

March 10, 2017

Marlene H. Dortch
Federal Communications Commission
Office of the Secretary
445 12th Street, SW
Washington, DC 20554

Re: Comments of Cardinal Health, Inc. in Opposition to Petition of Craig Moskowitz and Craig Cunningham in *In the Matter of Rules and Regulations Implementing the Telephone Consumer Protection Act*, CG Docket Nos. 02-278, 05-338, DA 17-144.

Dear Ms. Dortch:

Cardinal Health, Inc. ("Cardinal Health") appreciates the opportunity to comment on the petition filed by Craig Moskowitz and Craig Cunningham seeking a rulemaking and declaratory ruling related to the definition of prior express consent ("express consent") under the Telephone Consumer Protection Act ("TCPA").[1] Petitioners ask the Commission to abandon its longstanding express consent standard in favor of a standard that would require written consent—or similarly onerous oral consent—for all calls made to cell phones using an automatic telephone dialing system ("ATDS") or prerecorded message.

Cardinal Health respectfully requests that the Commission deny the Petition. The current standard aligns with Congressional intent and serves the public interest by facilitating the dissemination of important and wanted information to patients, thereby improving health outcomes for such patients. Moreover, given the significant impact any action on the Petition will have in the current unsettled TCPA regulatory environment, Cardinal Health respectfully requests that the Commission hold any action on the Petition in abeyance until both (i) *ACA International, et al. v. FCC*[2] has been fully adjudicated and the Commission has completed any necessary actions on remand, and (ii) the Commission has completed its ten-year regulatory review process.[3]

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[1] *In the Matter of Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991, Petition for Rulemaking and Declaratory Ruling of Craig Moskowitz and Craig Cunningham*, CG Docket Nos. 02-278, 05-338 (filed Jan. 22, 2017) ("Petition").

[2] *ACA International, et al. v. FCC*, Case No. 15-1211 (D.C. Cir.).

[3] *See* 82 Fed. Reg. 9282, 9293 (Feb. 3, 2017).

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I. Cardinal Health

Cardinal Health (NYSE: CAH) is a global health services and products company that brings scaled solutions to help its customers thrive in a changing world. It improves the cost-effectiveness of healthcare through solutions that improve the efficiency of the supply chain; optimize the process and performance of healthcare; provide clinically proven, daily use medical products and pharmaceuticals; and connect patients, providers, payers, pharmacists and manufacturers for seamless care coordination and better patient management. Backed by nearly 100 years of experience, Cardinal Health ranks among the top 50 on the *Fortune* 500 and among the *Fortune* Global 100. Cardinal Health has more than 37,000 employees in nearly 60 countries worldwide who are dedicated to improving the healthcare industry.

II. Petitioners' Request is Contrary to 25 Years of Precedent and was Previously Considered and Rejected by the Commission

The TCPA prohibits, subject to limited exemptions, calls to cell phones using an ATDS or prerecorded message without the called party's express consent.[4] Under Commission regulations, written consent is required for such calls if made for telemarketing or advertising purposes.[5]

Congress did not define express consent in the TCPA, thereby leaving it to the Commission to define the term. The Commission did so in its *1992 Report and Order* ("1992 Order") where it held that "persons who knowingly release their phone numbers have in effect given their invitation or permission to be called at the number which they have given, absent instructions to the contrary."[6] The Commission's position that voluntarily providing one's phone number constitutes express consent has stood for 25 years and been repeatedly reaffirmed. For example, in 2008, the Commission confirmed that "the provision of a cell phone number to a creditor, e.g. as part of a credit application, reasonably evidences prior express consent by the cell phone subscriber to be contacted at that number regarding the debt."[7] The Commission readopted the definition once again in its 2015 Omnibus Declaratory Ruling and Order ("2015 Order").[8]

Petitioners ask the Commission to abandon 25 years of precedent by adopting a written consent standard for non-telemarketing calls. The Commission previously rejected this onerous standard because it "would unnecessarily restrict consumer access to information communicated through purely informational calls."[9]

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[4] 47 U.S.C. § 227(b)(1)(A)(iii).

[5] 47 C.F.R. § 64.1200(a)(2).

[6] *In the Matter of Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991*, CC Docket No. 92-90, FCC 92-443 at ¶ 33 (rel. Oct. 26, 1992).

[7] *In the Matter of Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991*, CG Docket No. 02-278, FCC 07-232, ¶ 9 (rel. Jan. 4, 2008) ("2008 Order").

[8] *2015 Order* at ¶ 52.

[9] *See In the Matter of Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991*, CG Docket No. 02-278, FCC 12-21, ¶ 21 (rel. Feb. 15, 2012) ("2012 Order").

III. Informational Healthcare Calls are Overwhelmingly Wanted Communications that Improve Patient Health and Serve the Public Interest

Businesses and consumers have relied upon the Commission's express consent standard to build mutually-beneficial communicative relationships. Given the predominance of wireless device usage (over 377 million wireless devices in the U.S. with 49.3% of U.S. households being wireless-only),[10] it is critically important to be able to reach consumers via their wireless devices. This is especially true for healthcare related communications sent to patients. For example:

- Cardinal Health's subsidiary Medicine Shoppe International, Inc. ("Medicine Shoppe") is a franchisor of independent community pharmacies. These pharmacies use calls and/or texts to send important patient communications, including reminders to pick up or refill prescriptions and immunization reminders, among others. Non-adherence with medication poses a significant threat to patient safety and burdens the overall healthcare system. It is estimated that non-adherence causes approximately 125,000 deaths per year and is responsible for up to 10% of all hospitalizations.[11] Studies, however, show that reminder programs improve medication adherence and health outcomes for patients.[12] For example, a study funded by the Health and Human Services Agency for Healthcare Research and Quality concluded that prescription refill reminders sent via automated telephone calls "significantly increased adherence" to statins and other cardiovascular disease medications, leading to significantly lower cholesterol levels among at-risk patients.[13]

- Cardinal Health's Specialty Pharmacy supplies expensive and chemically-fragile medications to patients with complex and often life threatening illnesses such as cancer and immune disorders. Many times, the medications must be maintained in a temperature controlled environment and shipped under very specific handling protocols. These medications may not be left unattended; therefore, Cardinal Health calls each patient to confirm the delivery address and ensure someone will be available to take receipt of the medication at delivery. Without these calls, patients may not receive critical medications or may receive spoiled medications, putting such patients at risk.

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[10] *CTIA's Wireless Industry Summary Report, Year-End 2015 Results*, available at http://www.ctia.org/industry-data/ctia-annual-wireless-industry-survey (last accessed Feb. 22, 2017).

[11] M. Viswanathan, *et al.*, "Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States: A Systematic Review," *Ann Intern Med* (2012);157(11):785-795, (Nov. 20, 2015), http://annals.org/article.aspx?articleid=1357338 (last accessed Mar. 3, 2017).

[12] *See e.g.*, A. Iuga, *et al.*, "Adherence and Health Care Costs," Risk Management and Health Care Policy (2014): 40, available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3934668/pdf/rmhp-7-035.pdf (last accessed Mar. 3, 2017); D. Perlroth, *et al.*, "Medication Therapy Management in Chronically Ill Populations: Final Report Prepared for CMS" (August 2013) at 9, 83, 113, available at https://innovation.cms.gov/files/reports/mtm_final_report.pdf (last accessed Mar. 3, 2017).

[13] M. Vollmer, *et al.*, "Improving Adherence to Cardiovascular Disease Medications With Information Technology," *Am J Manag Care* (2014);20 (11 Spec No. 17):SP502-SP510, (Nov. 18, 2015), http://www.ajmc.com/journals/issue/2014/2014-11-vol20-SP/Improving-Adherence-to-Cardiovascular-Disease-Medications-With-Information-Technology/ (last accessed Mar. 3, 2017).

- Cardinal Health's direct-to-consumer medical products division uses calls to provide important information to patients who purchase diabetic, ostomy, mobility and wound care supplies. Cardinal Health uses these messages to verify the patient's delivery address, confirm delivery and remind them when it is time to reorder consumable supplies. Cardinal Health also contacts patients when their product is no longer available or the patient has experienced a change in insurance coverage that may require a change in product. Without these vital communications, patients may not be aware that there is a problem with their product delivery schedule until they run out of supplies.

- Cardinal Health's OutcomesMTM business provides, or arranges for independent pharmacists to provide, medication therapy management ("MTM") services to patients on behalf of health plans. Pursuant to the Medicare Modernization Act of 2003, Medicare Part D prescription drug plans are *required* to provide MTM services to patients.[14] To comply with this law, health plans must use outbound calls and messages to connect patients with pharmacists. MTM services are designed to optimize drug therapy and improve health outcomes for patients through activities such as patient assessments, comprehensive medication reviews ("CMRs"), the formulation of medication treatment plans, monitoring the efficacy and safety of medication therapy, and enhancing medication adherence through patient empowerment and education. A recent analysis performed by OutcomesMTM demonstrates that MTM programs can increase medication adherence by up to 13%.[15]

Not only do patients benefit from these informational communications, they expect and have come to rely upon notifications that their prescriptions are ready to be picked up, that it is time to refill prescriptions or physician-ordered medical supplies, and/or that critical medications or medical supplies have shipped. The same is true for calls related to MTM services. A recent survey indicates that 78% of members found CMRs to be helpful and 86% of members that received a recommendation from their pharmacist intended to follow it.[16] The overwhelming acceptance and desire for these important patient communications is further evidenced by the low opt-out rates. For example, in 2016, the overall opt-out rate for Cardinal Health's Specialty Pharmacy was 1.38%. Others have reported similarly low opt-out rates.[17]

[14] 42 C.F.R. § 423.153.

[15] Analysis based on adherence intervention for CareSource Medicaid and Exchange members taking medications to treat diabetes, hypertension or cholesterol, who were identified as at risk of becoming or already non-adherent. Adherence rates for members that successfully completed a targeted intervention program ("TIP") in 2015 were 11% (members taking cholesterol medication) to 13% (members taking diabetes or hypertension medication) higher than members that did not complete a TIP in 2015.

[16] Based on Blue Shield of California survey conducted in 2015 to Medicare members who received a CMR.

[17] *See, e.g.*, Joint Petition of Anthem, Inc., Blue Cross Blue Shield Association, WellCare Health Plans, Inc., and the American Association of Healthcare Administrative Management for Expedited Declaratory Ruling and/or Clarification of the 2015 TCPA Omnibus Declaratory Ruling and Order, CG Docket No. 02-278, filed July 28, 2015 (Anthem Petition), reporting 1.5% and .35% opt-out rates for Walgreens and Anthem, respectively.

IV. A Written Consent Standard Unnecessarily Hinders Healthcare Communications While Providing Little-to-No Consumer Protection Benefits

Petitioners downplay the significance of their requests by arguing that businesses may place live, individually dialed calls to cell phones and/or obtain individuals' written consent for non-marketing calls made using an ATDS or prerecorded message. The reality, however, is that neither scenario is practicable.

For many types of communications, manual dialing is either time or cost prohibitive. There is not enough time to place thousands (or even millions for some companies) of hand dialed telephone calls to provide information to patients in a timely manner. Even if time-sensitivity were not an issue, it is cost-prohibitive to hire thousands of employees or contractors to make such calls. Simply put, automated technology is necessary to convey these important healthcare messages. Petitioners also ignore that, in light of the Commission's 2015 Order (holding that "the capacity of an [ATDS] is not limited to its current configuration but also includes its potential functionalities"),[18] it is virtually impossible for a caller to know for sure whether calls are made using an ATDS.

Obtaining written consent is similarly impracticable in many situations. For instance, pharmacies and medical product suppliers often receive patient information through an intermediary such as a physician. With the rise of electronic prescribing, patients do not often bring paper prescriptions into pharmacies. Instead, the patient instructs the prescriber to send their information and the prescription electronically to their pharmacy of choice. In fact, the State of New York now *requires* physicians to use electronic prescribing.[19] Pharmacies and medical product suppliers often need to contact patients prior to having face-to-face contact with them; however, the businesses have no way to know whether the prescriber obtained the patient's written consent for such communications. Furthermore, the lack of a contractual relationship between the various prescribers and the pharmacy or medical product suppliers makes it impossible for them to require each prescriber to obtain written consent.

Even in situations where it might be theoretically possible to obtain written consent for critical patient communications, it would be unduly burdensome to do so. Consider, for example, prescription drug plans that must provide MTM services to their members. Implementing procedures to get written consent from millions of current members would involve an incredible amount of time and resources, resulting in increased healthcare costs. Moreover, it is likely that drug plans would not be able to get written consent from many patients—even those that want to receive beneficial MTM calls—because patients may not read or fully understand the plans' consent requests.

[18] *2015 Order* at ¶ 16.

[19] NY CLS Educ. § 6810(10).

Petitioners might point out that the partial exemption in 47 C.F.R. § 64.1200(a)(2) for healthcare messages made by or on behalf of a covered entity or business associate (as defined under the HIPAA Privacy Rule) would remain intact under their proposed rule amendment. Calls that qualify for this partial exemption are subject to the express consent standard rather than the written consent standard. This argument, however, ignores that pharmacies and other healthcare providers are currently defending TCPA lawsuits claiming that certain communications (e.g. flu shot and other immunization reminders) do not qualify for the partial exemption.[20] Additionally, as discussed below, the proposed definition of express consent is equally impracticable.

The full exemption for exigent healthcare messages provided by the Commission in its 2015 Ruling[21] is also unworkable in many situations. For example, some messages must exceed the maximum length permitted under the exemption (60 seconds or 160 characters) in order to convey all required information. In other situations, such as address verification calls, the permitted frequency of communications (1 per day and 3 per week) may be insufficient if the patient does not timely respond. Moreover, there is uncertainty as to the applicability of the exemption to exigent healthcare communications other than those specifically listed in the 2015 Order (e.g. address verification calls, medical equipment reminders, notifications related to changes in insurance coverage, etc.). With such uncertainty, companies cannot be confident that essential patient communications are covered under this narrow exemption.

Without viable exemptions or alternatives, a written consent standard would significantly hinder companies' willingness to send important healthcare messages to patients and patients' ability to receive the underlying information. As reported by WebRecon LLC, 4,860 TCPA lawsuits were filed in 2016 which is more than the number of TCPA lawsuits filed in 2007-2013 combined.[22] Between just 2015 and 2016, TCPA filings increased 31.8%.[23] TCPA settlements have reached as high as $75 million.[24] Given the significant risk of TCPA litigation, many companies will forego informative messages to consumers/patients rather than risk multi-million dollar lawsuits. This will lead to worse health outcomes for patients and substantially increase healthcare expenses nationwide.[25] These societal costs are too steep a price to pay so that a tiny fraction of the population is not required to take minimal effort to state up front that they do not

[20] *See e.g., Zani v. Rite Aid Hdqtrs. Corp.*, Case No. 14-cv-9701 (S.D. NY); *Lowe v. CVS Pharm., Inc.*, Case No. 1:14-cv-3687 (N.D. Ill.).

[21] *2015 Order* at ¶¶ 147-148.

[22] *2016 Year in Review: FDCPA Down, FCRA & TCPA Up* (WebRecon LLC, Jan. 24, 2017), available at https://webrecon.com/2016-year-in-review-fdcpa-down-fcra-tcpa-up/ (last accessed Feb. 22, 2017).

[23] *Id.*

[24] *$75M Capital One TCPA Class Deal OK'd; Attorneys' Fees Cut from $22M to $15M* (Bloomberg BNA, Feb. 23, 2015), available at https://www.bna.com/75m-capital-one-n17179923290/ (last accessed Feb. 22, 2017).

[25] Medication non-adherence causes up to $290 billion in increased healthcare costs every year due to preventable medical complications and resulting physician visits and hospitalizations. *See* New England Healthcare Institute, "Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease," Research Brief (August 2009), available at http://www.nehi.net/writable/publication_files/file/pa_issue_brief_final.pdf (last accessed Mar. 3, 2017). Any reduction in healthcare providers' ability to remind patients to refill their medication or order more of their medical products will only exacerbate this problem.

want to be contacted at the number they provide or to opt-out of receiving communications. The real benefactors of a written consent requirement will be class action attorneys and professional plaintiffs, not consumers.

V. Petitioners' Proposed Express Consent Definition is Equally Detrimental

Petitioners also offer an amended express consent definition.[26] Under their primary proposal, this definition applies only to calls made on behalf of a non-profit and limited healthcare messages.[27] Under its "alternative" proposal, the express consent definition applies to all calls except those made for telemarketing or advertising purposes.[28] The proposed definition, however, is the functional equivalent of a written consent standard.

To begin with, the proposed definition comingles the consent requirements for marketing and non-marketing calls. To obtain express consent (the standard for non-marketing calls), a caller must affirmatively disclose that the person is agreeing to receive ***advertising and telemarketing*** calls, even if it has no intention of making such calls.[29] This is extremely confusing and makes it less likely that an individual will provide consent for non-marketing calls that they actually want.

Moreover, the proposed definition requires, as a prerequisite to obtaining express consent, additional disclosures to be provided to consumers.[30] These disclosures mirror those required under the existing written consent definition (that calls will be made using an ATDS or prerecorded voice and that the individual is not required to provide consent as a condition of purchase).[31] Importantly, the Commission and various courts have held that a caller must prove that it had proper consent for each communication.[32] To do so, callers will need to prove that the mandatory disclosures were provided to each individual. That will likely require recorded telephone calls or written/electronic consent forms. The Petitioners' proposed express consent definition will, therefore, place businesses at the same level of risk and result in the same types of barriers to communication as the proposed written consent requirement.

By denying the Petitioners' proposed express consent definition, the Commission will act in the public interest and preserve the free flow of communications between healthcare companies

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[26] *Petition* at 48-49, 58.

[27] *Petition* at 42.

[28] *Petition* at 51.

[29] *Petition* at 48-49, 58.

[30] *Id*.

[31] *Id*.

[32] *See e.g., Chyba v. First Fin. Asset Mgmt.*, 2013 U.S. Dist. LEXIS 165276, **28-29 (S.D. Cal. Nov. 20, 2013)(*citing Robbins v. Coca-Cola-Co.*, 2013 U.S. Dist. LEXIS 72725, 2013 WL 2252646, *2 (S.D. Cal. May 22, 2013)) ("Prior express consent is an affirmative defense to be raised and proved by a TCPA defendant."); *In the Matter of Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991*, CG Docket No. 02-278, WC Docket No. 07-135, FCC 15-72, ¶ 81 (rel. July 15, 2015) ("We reiterate that the TCPA places no affirmative obligation on a called party to opt out of calls to which he or she never consented; the TCPA places responsibility on the caller alone to ensure that he or she have valid consent for each call made using an autodialer, artificial voice, or prerecorded voice.").

and the patients they serve. These communications provide a vital link between the company and the patient. Without being able to remind patients to refill their medications, confirm that patients are home to accept delivery of specialized medication or inform patients when the medical product they rely on has been discontinued and they need to select a new one, patients will suffer worse health outcomes and our healthcare system will be burdened by otherwise preventable complications, illnesses, hospitalizations and deaths each year.

VI. The Commission's Express Consent Standard Comports with Congressional Intent and Common Sense

Congress never intended for the TCPA to act as a bar to "expected or desired communications between businesses and their customers."[33] Rather, the TCPA is supposed to "balance[e] the privacy rights of the individual and the commercial speech rights of the telemarketer."[34] Yet, if the Commission grants the Petition, expected and desired communications will be effectively barred.

Congress did not define express consent in the TCPA. Instead, the Commission has discretion to determine what express consent requires. As previously explained, the Commission took the position that "persons who knowingly release their phone numbers have in effect given their invitation or permission to be called at the number which they have given, absent instructions to the contrary."[35] This standard is supported by the Congressional record which notes that "the called party has in essence requested the contact by providing the caller with their telephone number for use in normal business communications."[36] The standard is also supported by common sense. The act of voluntarily providing a phone number to another party (directly or through an authorized intermediary) is an affirmative act that, absent instructions to the contrary, demonstrates that the person has expressly consented to receive calls at that number.

For nearly 25 years, the Commission has continually revalidated that the act of giving a phone number to a person qualifies as express consent to be called at that number.[37] The Commission's balanced approach to the consent required for non-telemarketing communications aligns with Congress' intention that the TCPA should not prevent expected or desired communications between businesses and their customers. If the Commission grants the Petition,

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[33] *Report of the Energy and Commerce Committee of the U.S. House of Representatives*, H.R. Rep. 102-317, at 10 (1991) ("House Report").

[34] *House Report* at 17.

[35] *1992 Order* at ¶ 33.

[36] *House Report* at 13.

[37] See e.g. *2008 Order* at ¶ 9 ("We conclude that the provision of a cell phone number to a creditor, e.g., as part of a credit application, reasonably evidences prior express consent by the cell phone subscriber to be contacted at that number regarding the debt."); *2012 Order* at ¶ 21 (…we conclude that requiring prior express written consent for all such calls would unnecessarily restrict consumer access to information communicated through purely informational calls."); *2015 Order* at ¶ 52 ("For non-telemarketing and non-advertising calls, express consent can be demonstrated by the called party giving prior express oral or written consent or, in the absence of instructions to the contrary, by giving his or her wireless number to the person initiating the autodialed or prerecorded call.").

it will violate this important principle. Only by denying the Petition can the Commission continue to fulfill Congress' intent.

VII. Conclusion

Preservation of the health and safety of Americans should be at the forefront of the Commission's collective mind when evaluating the Petition. If the Commission grants either of the Petitioners' requests, it will significantly hinder messages that are vital to patients' wellbeing and, in some instances, their lives. Given the seriousness of the Petition and the profound impact any action on it would have, Cardinal Health respectfully urges the Commission to hold any action on it in abeyance until several other serious TCPA matters are resolved.[38] Specifically, the Commission should not act on the Petition until (i) *ACA International, et al. v. FCC* has been fully adjudicated and the Commission has completed any required actions on remand, and (ii) the Commission has completed its ten-year regulatory review.

When the time comes to act on the Petition, Cardinal Health respectfully requests that the Commission deny it in its entirety.[39] The Commission's denial of the Petition will demonstrate its commitment to protecting the health and wellbeing of Americans while fulfilling Congress' intent in passing the TCPA.

[38] The Commission's denial of the Petition may not seem significant, but Petitioners would likely appeal the denial thereby triggering a drawn-out battle in the courts and uncertainty in the business community. Delaying the denial until after other significant regulatory uncertainties have been resolved would reduce the impact of the uncertainty created by such an appeal. *See WWHT, Inc. v. Federal Communication Commission*, 656 F.2d 807, 814 (D.C. Cir. June 18, 1981) ("While we agree that judicial intrusion into an agency's exercise of discretion in the discharge of its essentially legislative rulemaking functions should be severely circumscribed, we reject the suggestion that agency denials of requests for rulemaking are exempt from judicial review.").

[39] On January 30, 2017, President Trump directed all federal agencies to identify two existing regulations to be repealed for each new regulation published for notice and comment. E.O. 13771, § 2(a). In so doing, he identified that "it is the policy of the executive branch to be prudent and financially responsible in the expenditure of funds" including "the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations." E.O. 13771, § 1. President Trump reiterated his commitment to regulatory reform on Feb. 24, 2017 by directing each agency to appoint a Regulatory Reform Officer to oversee the implementation of regulatory reform initiatives. E.O. 13777, § 2. The Commission should also deny the Petition out of respect for the President's policy of relieving regulatory burdens on commerce.

Thank you for the opportunity to comment and for your consideration of Cardinal Health's recommendation.

Sincerely,

Nicholas R. Whisler, Esq.
Michele A. Shuster, Esq.
Joshua O. Stevens, Esq.
Counsel for Cardinal Health, Inc.